

<p style="text-align: center;">Department of Energy Office of Worker Protection Programs and Hazards Management Radiological Control Technical Position RCTP 2000 - 04</p>
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Acceptable Approach for Controlling and Labeling Radioactive Material

Issue:

The occupational radiation protection regulations established by the Department of Energy (DOE) and Nuclear Regulatory Commission (NRC) are similar in many respects. However, there are significant differences in some of the values used for controlling and labeling radioactive items and containers of radioactive material, including sealed radioactive sources. Because radioactive materials are frequently transferred between DOE-regulated and NRC-licensed activities, some DOE contractors have raised questions regarding measures to ensure compliance.

Note: Throughout this document, references to NRC requirements and licensing activities also include equivalent activities undertaken by the States under NRC's Agreement State Program.

Introduction:

The 1998 amendment of Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection* (10 CFR 835), includes requirements for controlling and labeling radioactive items and containers of radioactive materials, including sealed radioactive sources. NRC establishes similar, but not identical, requirements for radioactive material control and labeling (applicable to NRC licensees) in various Parts of 10 CFR, including Parts 20, 30, 31, and 32.

Title 10 CFR 835.605 establishes requirements for labeling radioactive items and containers of radioactive material. Paragraph 835.606(a)(2) provides an exception for items and containers of radioactive material when the total quantity of radioactive material present is less than one tenth of the threshold values provided in Appendix E of 10 CFR 835. Some of the labeling threshold values derived from Appendix E of 10 CFR 835 vary significantly from the corresponding labeling threshold values established by NRC [see 10 CFR 20, Appendix C]. Note that the labeling requirements of § 835.605 are augmented by the ALARA provisions of §§ 835.101(b) and 835.1003(b), and the general sealed source control requirements of § 835.1201.

The great majority of DOE activities are exempted from NRC regulations (for example, see 10 CFR 30.11 and 30.12). Because of the differing control and labeling requirements between DOE and NRC, situations of non-compliance with applicable regulations (either NRC or DOE) may arise when radioactive material is transferred between DOE-regulated and NRC-licensed facilities.

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Requirements:

Applicable Requirements (based on the November 4, 1998 amendment to 10 CFR 835)

§ 835.2(a) Definitions

Accountable sealed radioactive source means a sealed radioactive source having a half-life equal to or greater than 30 days and an isotopic activity equal to or greater than the corresponding value provided in Appendix E of this part.

Sealed radioactive source means a radioactive source manufactured, obtained, or retained for the purpose of utilizing the emitted radiation. The sealed radioactive source consists of a known or estimated quantity of radioactive material contained within a sealed capsule, sealed between layer(s) of non-radioactive material, or firmly fixed to a non-radioactive surface by electroplating or other means intended to prevent leakage or escape of the radioactive material. Sealed radioactive sources do not include reactor fuel elements, nuclear explosive devices, and radioisotope thermoelectric generators.

§ 835.101 Radiation protection programs

(c) The content of each RPP shall be commensurate with the nature of the activities performed and shall include formal plans and measures for applying the as low as reasonably achievable (ALARA) process to occupational exposure

§ 835.605 Labeling items and containers.

Except as provided at § 835.606, each item or container of radioactive material shall bear a durable, clearly visible label bearing the standard radiation warning trefoil and the words "Caution, Radioactive Material" or "Danger, Radioactive Material." The label shall also provide sufficient information to permit individuals handling, using, or working in the vicinity of the items or containers to take precautions to avoid or control exposures.

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§ 835.606 Exceptions to labeling requirements.

Items and containers may be excepted from the radioactive material labeling requirements of § 835.605 when:

(a) ...

(b) The quantity of radioactive material is less than one tenth of the values specified in appendix E of this part; or ...

§ 835.1003 Workplace controls.

(b) The ALARA process is utilized for personnel exposures to ionizing radiation.

§ 835.1201 Sealed radioactive source control.

Sealed radioactive sources shall be used, handled, and stored in a manner commensurate with the hazards associated with operations involving the sources.

Discussion:

As a result of differing regulatory objectives and approaches, there are some significant differences in the values used for controlling and labeling radioactive items and containers of radioactive material, including sealed radioactive sources¹. In practice, the differing radioactive material labeling threshold values and control requirements should not present significant compliance problems for DOE activities. As a result of the differing requirements, DOE activities may receive radioactive material from NRC licensees that is either labeled or unlabeled, consistent with the regulations and license requirements applicable to the provider. Cognizant individuals at DOE activities cannot make any assumptions regarding compliance with DOE labeling requirements based on the presence or absence of labels applied by the radioactive material provider. It is incumbent upon the affected DOE activity to implement appropriate controls, based on an assessment of the amount of radioactive material present and the planned activities.

¹The two agencies have used different maximum credible doses and exposure scenarios to derive their respective published labeling threshold values. Accordingly, for some radionuclides the radioactive material labeling threshold values vary between the two agencies. While most of the DOE and NRC values are relatively similar, in some cases the variance between the values is great, with some 10 CFR 835 values being significantly less than, and others significantly greater than, the corresponding 10 CFR 20 values.

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If a labeled item or container is received from a radioactive material provider and it is subsequently determined, through survey and/or analysis, that labeling is not required by 10 CFR 835, a DOE activity may then choose to remove the label(s). However, there is no apparent reason to remove previously applied labels, and DOE believes that retention of provider-applied labels constitutes a best management practice².

This situation may be complicated somewhat in situations where material is routinely transferred between DOE regulated and NRC licensed facilities and activities. For example, sites where joint DOE-regulated and NRC-licensed activities occur or DOE operations or facilities that provide radiological services to NRC licensees such as production of radionuclides. There is no regulatory prohibition on the practice of implementing and releasing the applicable DOE- and NRC-required controls as the material moves between facilities and activities. However, in these situations DOE encourages sites to implement the more restrictive of either the NRC or DOE requirements.

DOE welcomes input from its operating entities regarding any operational or technical difficulties arising out of efforts to comply with existing requirements or opportunities to improve those requirements.

Technical Position:

When receiving radioactive material from NRC-licensed facilities, DOE activities are required to ensure that the ensuing storage, usage, and control of the material are consistent with the requirements of 10 CFR 835. Because of differences between DOE and NRC requirements for radioactive material labeling and control, radioactive material received from NRC licensees may or may not be received in a condition that is in compliance with DOE requirements, particularly the labeling requirements found in Subpart G of 10 CFR 835. Therefore, DOE activities should carefully assess the radiological characteristics of any received material and implement the controls required by 10 CFR 835. If the material is received with a label, consideration should be given to retaining the label; and if the material will be transferred frequently between DOE-regulated and NRC-licensed activities, consideration should be given to implementing and maintaining the most stringent requirements applicable to ensure ongoing compliance.

²Even though radioactive material may not require labeling under Appendix E of 10 CFR 835, such material is still subject to the other provisions of 10 CFR 835 intended to protect individuals from exposure to ionizing radiation. The use of non-mandatory labeling, thus, enhances radiation protection by reducing the chances for inadvertent exposure to radioactive material.

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References:

1. 10 CFR 835, *Occupational Radiation Protection*, U.S. Department of Energy, November 4, 1998.
2. 10 CFR 20, *Standards for Protection Against Radiation*, U.S. Nuclear Regulatory Commission, January 9, 1997
3. 10 CFR 30, *Rules of General Applicability to Domestic Licensing of Byproduct Material*, U.S. Nuclear Regulatory Commission, May 16, 1996
4. 10 CFR 31, *General Domestic Licenses for Byproduct Material*, U.S. Nuclear Regulatory Commission, December 22, 1993
5. 10 CFR 32, *Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material*, U.S. Nuclear Regulatory Commission, May 9, 1995
6. DOE G 441.1-10, *Posting and Labeling for Radiological Control*, U.S. Department of Energy, May 1999.